ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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VIA EMAIL

June 1, 2016

Mr. Jerry Menikoff
Director, Office for Human Research Protections
Department of Health and Human Services
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Dear Director Menikoff:

On October 7, 2015, the U.S. House of Representatives passed H. Res. 461, which created the Select Investigative Panel and empowered the panel to conduct a full and complete investigation regarding the medical practice of abortion providers and the business practices of firms that procure and resell fetal tissue.

During the course of our investigation, we have uncovered documents and received testimony from confidential informants indicating that StemExpress, LLC ("StemExpress"), a for-profit firm which procures fetal tissue from abortion clinics and transfers it to research customers, violated 45 CFR 46 by using the appearance of compliance with the regulations, while fraudulently using invalid consent forms, and misleading customers to believe it had a valid Institutional Review Board ("IRB") approval.

In addition to this letter, I have included as Attachment A another referral to the U.S. Department of Health and Human Services, Centralized Case Management Operations.

Background

StemExpress was founded in 2010 as a for-profit company and continues operations as StemExpress Foundation. Through its corporate existence, StemExpress' activities were obtaining contractual relationships with abortions clinics for the purpose of embedding a StemExpress company employee inside the clinic. The employees had access to confidential patient medical records, which they used to obtain consent and procure fetal tissue. StemExpress then resold that tissue to researchers. StemExpress pays the abortion clinic a per-specimen fee and then marks up the specimen four to six hundred percent for sale to a research institution.

Stem Express' tissue procurement technicians embedded inside the abortion clinics had the following daily **work sequence**:

- A researcher / customer placed an order for human fetal tissue using an online business portal provided by StemExpress. The web portal allowed the customer to request a particular gestational range for the fetal tissue. (See Attachment B, "Researcher Procurement Record.").

- When it first began operations, the abortion clinics from which StemExpress procured fetal tissue faxed the next day's schedule of potential patients directly to the StemExpress tissue procurement technician assigned to the clinic. (See Attachment C, "Fax from The Alameda, San Jose [Planned Parenthood clinics] to StemExpress, Jan. 10, 2013.").

- The day the abortion procedures were scheduled, StemExpress emailed the procurement schedule to its tissue technicians. (See Attachment D, "Updated Task Assignment: Procurement Schedule Wednesday, 3/30/13.").

- Emails produced by StemExpress demonstrate that its employees knew beforehand protected health information, including gestation periods of fetuses. For example: On January 6, 2015, a StemExpress employee emailed a customer that: "There are no patients that qualify for your request today. You will be on the schedule again for tomorrow, but the cases are all low gestation." On January 14, 2015, at 12:40 p.m., a StemExpress employee emailed a researcher: "Unfortunately, there is nothing within your gestational requirements today. There will be some potentials tomorrow, would you like to be on the schedule?" Hours later, the customer emailed: "Yes, please put me on the schedule for tomorrow." On April 14, 2015, a StemExpress employee emailed a researcher: We have a trisomy patient scheduled for this week and could try to procure a brain sample for you . . . ." (See Attachement E, "Emails.").

- As the firm became more computerized, tissue procurement technicians logged into a Website. (See Attachement F, "Navigating The Task Board.").

- The StemExpress procurement technician then sought out particular patients by name and obtained their consent to donate fetal tissue while they were awaiting their procedures. (See Attachment G, "Clinic Procedures and Policies.").

- StemExpress procurement technicians were paid an hourly wage and a per tissue "bonus" for each item they procured from the order page. (See Attachment H, "Procurement Technician Compensation Policy for Tissue and Blood Procurement.").

- StemExpress paid the abortion clinic a per tissue fee and then marked up the tissue four to six hundred percent for sale to the researcher. (See Attachment I, "StemExpress Services Agreement with Planned Parenthood Shasta Pacific," "StemExpress Services Agreement with Planned Parenthood of Santa Barbara, Ventura & San Luis Obispo Counties;" and Attachment J, "Purchase Order No. 60856806," "Purchase Order No. 3000014694," "Purchase Order No. 60836838," "Purchase Order No. 60858758," and "StemExpress Invoice # 1439.").

Documents produced to the Panel prove that StemExpress' tissue procurement technicians knew in advance of the abortion schedules, the clinics assisted them with obtaining consent, and the entire work flow was designed to maximize the firm's profits. For example instructions to the tissue procurement technicians (See Attachment K, "Standard Operating Procedure") states:

> The day before [the abortion] surgery: Check WebOffice [apparently an earlier version of the Task Board] for research requests; Determine your location for the next day; Call the clinic to verify how many surgeries are scheduled . . . .
>
> The clinic staff will identify donors. It is the procurement technician's responsibility to retrieve the tissue and package it appropriately for the given researcher. It is also the procurement technician's responsibility to update WebOffice so everyone is aware what tissue has been obtained and for whom.
>
> . . . On the day of the surgery, the following steps are taken to procure tissue from POC [Products Of Conception; i.e., fetal tissue] . . . Print a copy of the day's Procurement Schedule. Following along the chart flow so you know what gestations to expect.
>
> . . . Keep track of [the] time [of procurement], gestation [age], fetal foot size or sono[gram] report and date.
>
> . . . If you have an excellent sample with no researcher listed on today's schedule, please contact [redacted] Stem Express' President and CEO] immediately, and

they will work to call researchers who may be interested even though they are not currently scheduled.

The work sequence, when combined with the supporting documents reveals that StemExpress did not have a medically valid reason to see, and the abortion clinics did not have a reason to provide, patients' protected health information ("PHI"). Instead, the abortion clinics shared patients' PHI with StemExpress in furtherance of contractual agreements that financially benefitted StemExpress and the clinics.

Informed Consent

HHS requires investigators to obtain informed consent from each human being used as a research subject.[1] The "basic elements of informed consent" include the following information:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; . . . [and]
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research . . .[2]

Documents produced by StemExpress to the Select Panel indicate the firm did not follow those regulations. One of those documents is Attachment L, "A Form for Informed Consent To Participate In A Clinical Research Study, involving the donation of aborted pregnancy tissue for medical research, education, or treatment." It states:

> Research using donated tissue and blood is currently underway to uncover the causes of and ultimately find cures for things like: Heart Disease, Diabetes, Parkinson's Disease, Sickle Cell Anemia, Leukemia, Lymphoma, Cancer, Spinal Cord Disease, and more. . . .
>
> The benefits of consenting to donation today include furthering medical research in finding cures for disease like diabetes, leukemia, lymphoma, Parkinson's disease and more.

The Panel notes that the StemExpress consent form specifically does not conform to the General requirements for informed consent mandated under 45 CFR 46 §116. Witnesses at a recent Select Panel hearing agreed that forms similar to the one StemExpress used apparently do not conform to the HHS regulations on informed consent.[3]

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[1] 45 CFR 46 §116.

[2] *Id.*

[3] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

Coercion or Undue Influence

The requirements for informed consent further state that investigators "shall seek such consent only under circumstances that provide the prospective subject with . . . sufficient opportunity to consider whether or not to participate and that **minimize the possibility of coercion or undue influence.**" [emphasis added].[4]

The regulations further state: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as . . . pregnant women . . . additional safeguards" are included.[5] Documents produced by StemExpress indicate the firm only obtained fetal tissue from women who had undergone abortions at abortion clinics, and the company's employees were the ones obtaining consent. It is unclear whether such consent occurred before or after the procedures was conducted.

Additional documents produced by StemExpress demonstrate that tissue procurement technicians engaged in real-time email correspondence with researchers while abortions were taking place - presumably before they obtained informed consent to procure fetal tissue - and yet StemExpress employees already were promising to deliver products of conception. (See Attachment M, "Emails regarding PO # 60858758."). The emails reveal that a customer had placed an order for a skull and limbs.

On January 22, 2015, at 12:26 p.m., the customer emailed a StemExpress employee stating: "Just wanted to check in and see if there are any cases within our gestation range for today? Need to book some time on the equipment if so." Within minutes, at 12:30:11 p.m., the StemExpress employee replied: "There is one case currently in the room, I will let you know how the limbs and calvarium [skull] look to see if you are able to take them in about fifteen minutes." Less than two minutes later, the customer wrote: "Great thank you so much." At 1:20:32 p.m., the StemExpress employee informed the customer: "The calvarium is mostly intact, with a tear up the back of the suture line, but all pieces look to be there. The limbs, one upper and one lower, are totally intact, with one upper broken at the humerus, and one lower broken right above the knee. Please let me know if these are acceptable. I have set them aside and will await your reply." Approximately five minutes later, the customer replied: "That sounds great we would like both of them. Please send them our way. Thanks again . . ." The StemExpress employee responded: "Limbs and calvarium will be there between 3:30 and 4:00."

The fact that StemExpress was attempting to interest a customer in fetal body parts **before an abortion had taken place** raises serious concerns that there may have been coercion or undue influence upon the patient to consent to procurement. Both Members and witnesses at our recent hearing raised the same question.[6]

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[4] 45 CFR 46 §110(4) and (7)(b).

[5] *Id.*

[6] See generally House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016.

IRB

Documents produced by StemExpress violated 45 CFR 46 by misleading customers into believing it had a valid IRB approval. StemExpress obtained approval for its "study" from BioMed IRB (Seen Attachment N, "Informed Consent To Participate In A Clinical Research Study," and "BioMed IRB Continual Approval Notification.").

In fact, one of StemExpress' marketing materials advertises the firm provides clinics with "IRB Certified Consents," and that "Our IRB approved **protocols** and **consents** protect you as well as donor's privacy in accordance with HIPAA guidelines." (Attachment O, StemExpress marketing brochure.).

At our recent hearing, Dr. G. Kevin Donovan, the senior clinical scholar at the Kennedy Institute of Ethics at Georgetown University, and director of the Pellegrino Center for Clinical Bioethics at Georgetown University, said actions such as those undertaken by StemExpress "would never pass muster for an IRB."[7] Yet StemExpress purportedly had the approval of an IRB.

HHS regulations require IRBs to "prepare and maintain adequate documentation" of its activities, including:

> (1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
>
> (2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
>
> (3) Records of continuing review activities.
>
> (4) Copies of all correspondence between the IRB and the investigators . . . .[8]

On March 29, 2016, the Panel issued a subpoena to BioMed IRB which required it to produce documents sufficient to show BioMed IRB's ongoing oversight, within the definition of Title 45 Code of Federal Regulations Part 46, of any entity involved with fetal research or transplantation of fetal tissue for which it issued an IRB approval.[9]

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[7] House of Reps., Select Investigative Panel on Infant Lives, *Hearing on Bioethics and Human Tissue*, Mar. 2, 2016, at. P. 91.

[8] 45 CFR § 46.115 (a).

[9] House of Representatives, Select Investigative Panel on Infant Lives, Subpoena to Biomedical Research Institute of America, Mar. 29, 2016.

BioMed IRB's executive director informed the Panel on April 4, 2016 that, in regards to those records, "there are none."[10] This apparently is a direct violation of 45 CFR 46.

While regulation of IRBs does not fall under the auspices of OHRP, it may interest you to know that, in March of 2012, the Food and Drug Administration ("FDA") issued a warning letter to BioMed IRB, citing: A failure to fulfill membership requirements; failure to prepare, maintain, and follow adequate written procedures for conducting the review of research, including initial and continuing review; and keeping minutes that were not sufficient to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution. As a result, the FDA ruled it "will withhold approval of all new studies subject to 21 CFR Part 56 and reviewed by the IRB; and [n]o new subjects are to be enrolled in any ongoing studies subject to 21 CFR Part 56 and approved by the IRB."[11] That ban was lifted in January 2013.[12]

Given the facts outlined above, and the supporting documentation, I urge your office to conduct a thorough investigation into whether StemExpress violated 45 CFR 46, and, if OHRP agrees that such violations occurred, to take all appropriate actions.

Respectfully yours,

Marsha Blackburn
Chair, Select Investigative Panel

cc: Rep. Jan Schakowsky
Ranking Member

[10] Email from Fred Fox, Executive Director, Biomedical Research Institute of America, to Select Panel staff, Apr. 4, 2016.
[11] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Mar. 29, 2012.
[12] Letter from Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, to Fred Fox, Executive Director, Biomedical Research Institute of America dba BioMed IRB, Jan. 16, 2013.